

REMARKS

Entry of the foregoing, reexamination and further and favorable consideration of the subject application, in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.116, are respectfully requested.

Claims 7 and 24 have been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over Hersh (U.S. Patent No. 6,011,067). This rejection is respectfully traversed.

With regard to claim 7, the Examiner has acknowledged that Hersh does not explicitly teach a method of treating skin cancer utilizing EC SOD. However, relying on column 2 of Hersh, the Examiner has stated that the reference does teach that super oxides and free radical species are pathogenic of neoplasia, and that release of such oxy radicals may be inhibited by EC SOD.

The paragraph comprising the disclosure mentioned by the Examiner is as follows:

Psoriasis is characterized by hyper-proliferation and incomplete differentiation of epidermal keratinocytes. Psoralen plus ultraviolet A radiation A(PUVA) represents one form of therapy, albeit there exists an increased risk of photocarcinogenesis with this treatment. Like the increased risk of cutaneous carcinomas and melanoma from UV radiation, oxygen and other free radical species may be pathogenetic of these neoplasias. PUVA leads to chromosome breakage through the formation of transferable clastogenic factors, whose genesis may be inhibited by the enzyme superoxide dismutase. Elastogenic factors have been detected in patients with psoriasis and with other illnesses associated with oxidative stress...(omitted). Thus, it is hypothesized by the present invention that the oxidative stress in psoriasis and especially during PUVA treatment may be ameliorated and the risk of photocarcinogenesis decreased by administration both of oral and topical antioxidants (emphasis added).

Applicants respectfully submit that the underlined neoplasia designate psoriasis. The point of the paragraph is that the problem of oxidative stress of solaren+UV therapy for psoriasis may be ameliorated, and the risk of photocarcinogenesis decreased, by administration of both the oral and topical antioxidants of the Hersh patent. Also, Hersh discloses that "psoriasis is characterized by hyper-proliferation and incomplete differentiation of epidermal keratinocytes" (see the first sentence of the paragraph set forth above). Applicants submit that the "incomplete differentiation" mentioned in this sentence is a kind of neoplasia.

As noted above, the Examiner has stated that superoxide and other free radical species may be pathogenetic of neoplasia. However, the neoplasia described in the Hersh patent designate psoriasis. Furthermore, a person of ordinary skill in the art would not

reasonably predict that a compound useful for decreasing the risk of photocarcinogenesis would also be useful for treating skin cancer. Accordingly, Hersh does not teach or suggest that EC SOD would be useful for treating skin cancer.

Applicants have submitted herewith a Declaration of Dr. Kim, a named inventor of the present application. The experiments detailed in the Declaration show that EC-SOD induces phosphorylation of p38 and JNK (which inhibit cell proliferation) (Fig. 1 of the Declaration); increase the production of STAT1, p53 and FoxO3a (which inhibit cell proliferation); increase the production of p21, p27 and Rb (which inhibit cell cycle); and decrease the production of cycD and cycA (which induce cell cycle) (Fig. 3). Also, EC-SOD shows inhibitory effects on melanoma cell migration (Fig. 4). In Fig. 5 of the Declaration, IFN-g induced apoptosis increased by approximately 20% when A375 and HaCaT cells were treated with EC-SOD. It was also shown that EC-SOD has a similar effect on another human epithelial carcinoma cell line and primary keratinocytes. Additionally, the lungs from transgenic mice overexpressing EC SOD showed reduced metastasis of melanoma cells compared to wild type control mice, suggesting that EC-SOD has an inhibitory effect on the metastasis of melanoma cells. The results shown in the Declaration demonstrate that EC-SOD is surprisingly useful for treating cancer.

With regard to claim 24, this claim relates to a method for treating dermatitis or psoriasis, which comprises administering to a subject in need thereof an effective amount of a composition consisting of i) an isolated EC SOD protein or an expression vector comprising a polynucleotide encoding the EC SOD protein; and ii) pharmaceutically acceptable carrier, wherein the EC SOD protein comprises an amino acid sequence of SEQ ID NO: 11.

In contrast to the present claim, the suggested method of Hersh relates to a method for treating psoriasis utilizing psolarens and UVA. Applicants respectfully submit that the present method is technically significantly different from the reference method. In particular, a person of ordinary skill in the art would not reasonably predict, based on a method for using psolarens and UVA, that a method for using EC SOD would be useful for the intended purpose.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions related to this Amendment and Reply, or the application in general, it would be appreciated if the Examiner would telephone the

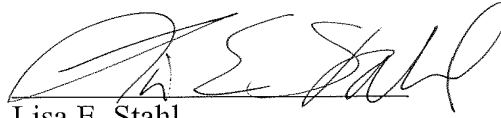
undersigned attorney at the below-listed telephone number concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: October 21, 2009

By:

A handwritten signature in black ink, appearing to read 'Lisa E. Stahl', written over a horizontal line.

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